2D Vaccine Barcode Pilot

2012 AIRA Annual Conference
September 19, 2012

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Outline

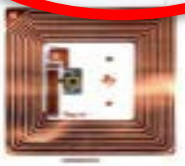
- What are 2D Barcodes?
- Why are 2D Barcodes Relevant to Registries?
- 2D Vaccine Barcode Pilot Overview & Update

Two-Dimensional (2D) Barcodes

- **General Information**
  - Read using image-based scanning
  - Expand relative to data quantity encoded
  - Store data horizontally and vertically
  - Some error correction capabilities
  - Dozens of 2D barcode symbologies exist

- **Significance to Vaccines**
  - Larger data capacity than linear barcodes
  - More information in a smaller space (on vials/syringes)

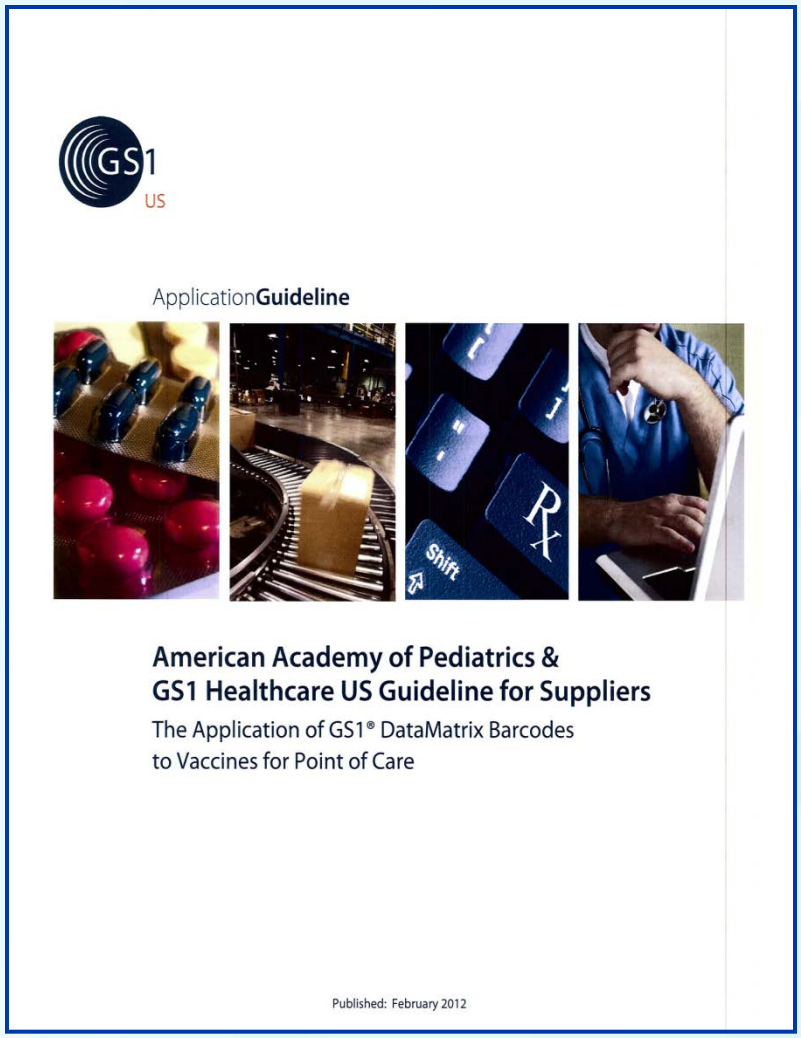
2D Barcode Symbology Examples

Type	Example	Data Characteristics	Use Case	Reader
Linear Barcode	 Databar Limited	▪ Maximum – 56 a/n chars	▪ Consumer products	Linear Scanner
Linear Barcode	 GS1-128	▪ Maximum 48 a/n characters	▪ Logistics units (SSCC) ▪ Pharmaceutical	Linear scanner
Quick Response (QR) Barcode		▪ Maximum 4296 a/n characters	▪ Consumer products	Image scanner
2D Datamatrix Barcode	 GS1 Datamatrix	▪ Max 2335 a/n characters	▪ Healthcare items ▪ Direct part	Image scanner
RFID	 Gen 2 Passive	▪ Typically contains 2048 characters	▪ Logistics	RFID reader

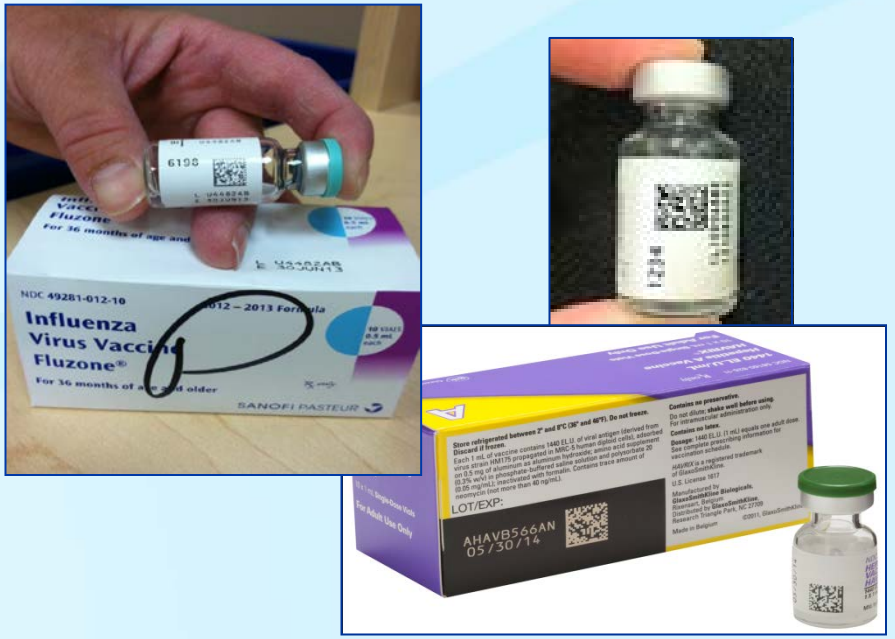
You will find this on pilot vaccines

Source: GS1 - 2011

GS1 DataMatrix for Vaccines



- AAP / GS1 collaboration
- Currently contains GTIN, Expiry Date and Lot Number
- GS1 DataMatrix symbology currently on multiple vaccines



http://www2.aap.org/immunization/pediatricians/pdf/barcoding_guidance_manufacturers_022212.pdf

GS1 Global Trade Item Number (GTIN)

- Globally unique GS1 Identification Number used to identify "trade items"
- Assigned by the brand owner or manufacturer of the product
- 14 digits:
  - 1st digit – Indicator digit for packaging (can be 0 filled)
  - Next 2 digits – 03, GS1 US Placeholder
  - Next 10 digits – National Drug Code (in the US)
  - Last 1 digit – Check Digit
- **Example**:

Scanned 2D Barcoded Vaccine Data Example

- 01**00349281589058**17**131028**10**U4275AA**
  - GTIN = 0034928158905
  - Expiration Date = 131028
  - Lot # = U4275AA
- GS1 Application Identifiers (AI)
  - 01 – GTIN
  - 17 – Expiry
  - 10 – Lot/Batch Number
- 01**00349281589058**17**131028**10**U4275AA**

Relevance to Registries

- **Needed for 2D Barcode Scanning Enablement**
  - Ability to Translate GTIN to NDC to CVX/MVX
  - Procedures to maintain GTIN to NDC mapping
  - Listening mode for scanning

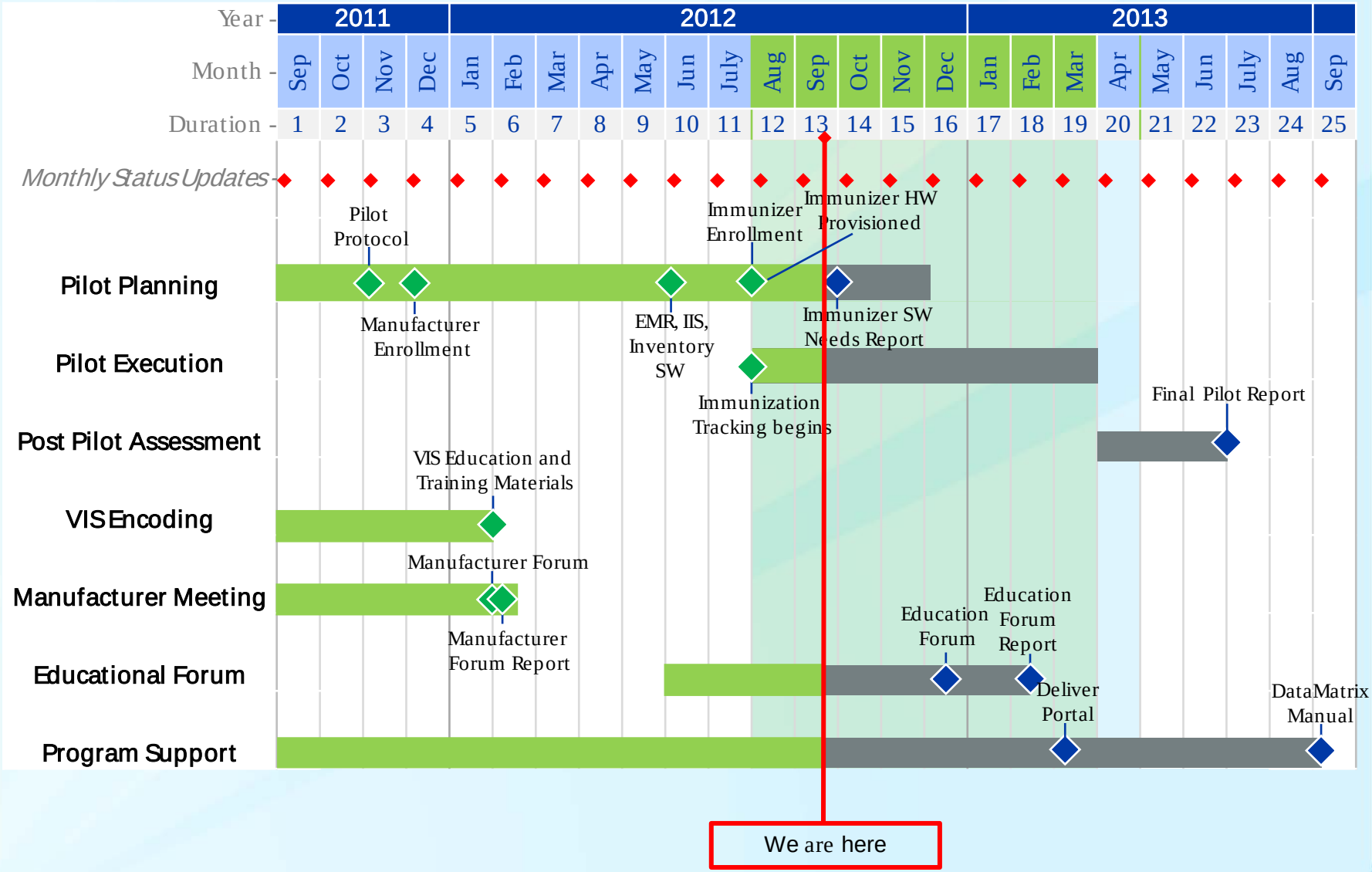
- **Recognized Need - Future Implementation**
  - IIS/EMR functional requirements documentation
  - Provision of technical support to non-pilot sites (providers & registries)

2D Barcode Vaccine Pilot

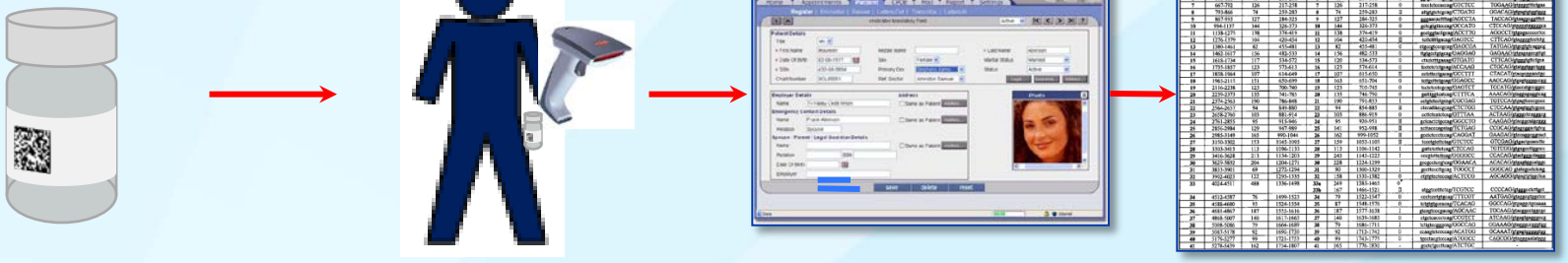
Objective: To assess the extent to which using 2D barcoded vaccines and scanners affect the completeness and accuracy of vaccine data collected by pilot sites.

- **Part 1** – Pilot Project to Implement 2D Barcodes on Vaccine Vials and Syringes
  - **Work Flow Analysis**
- **Part 2** – Incorporate 2D Barcodes onto Vaccine Information Statements (VIS)
- **Part 3** – Provide Technical Support and Guidance for Future Implementers

Project Timeline with Major Milestones



Pilot Implementation Information Flow



Manufacturer

Add a 2D barcode to the primary packaging:

- Data Matrix barcode to contain
  - GTIN*
  - Expiration date
  - Lot number
- Distribute to pilot participants

Immunizer

Record and track data:

- Scan barcode when inventorying and dispensing vaccine products and enter into the medical record

Record system

Medical record types:

- Electronic medical records (EMR)
- Custom applications
- Acts as a source of evaluation for data accuracy and completeness

IIS

Receive data from the immunizers' EMR or equivalent electronic system:

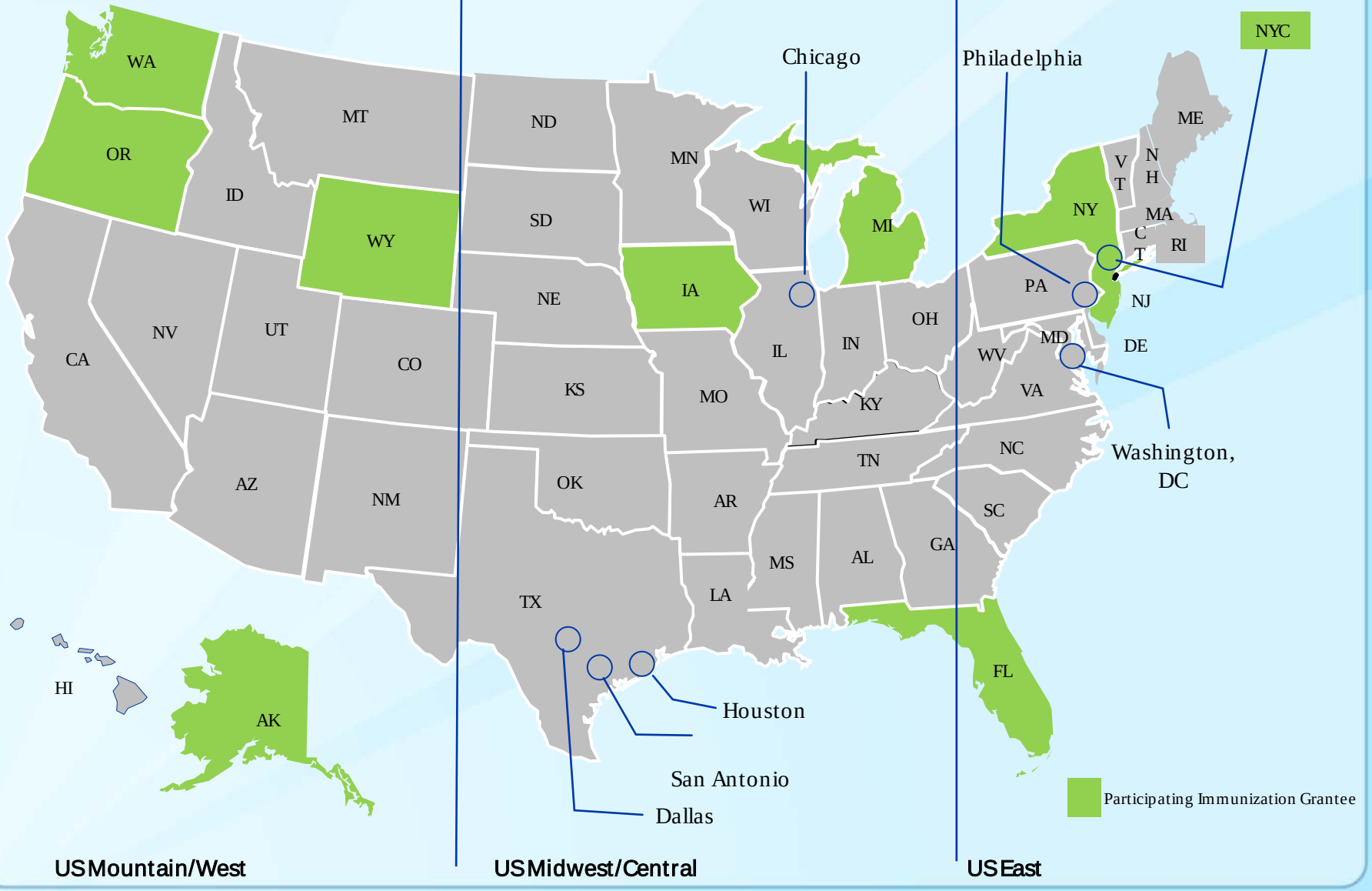
- Acts as a source of evaluation for data accuracy and completeness

**The Global Trade Item Number (GTIN) is a unique identifier used globally to identify an item. For vaccines and other health care products, the GTIN is specifically used to carry the National Drug Code (NDC)—a unique identifier used in the US as mandated by the FDA.*

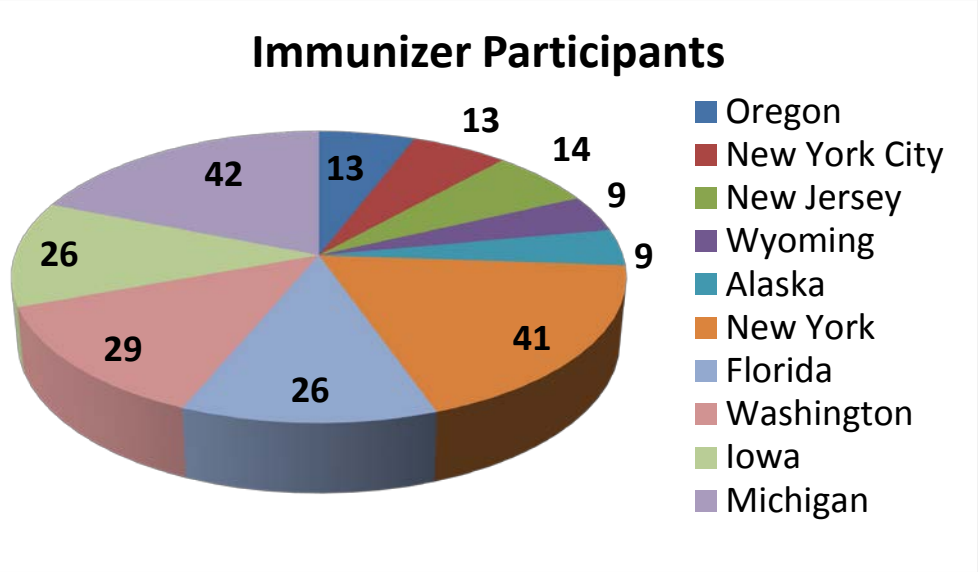
Pilot Participants

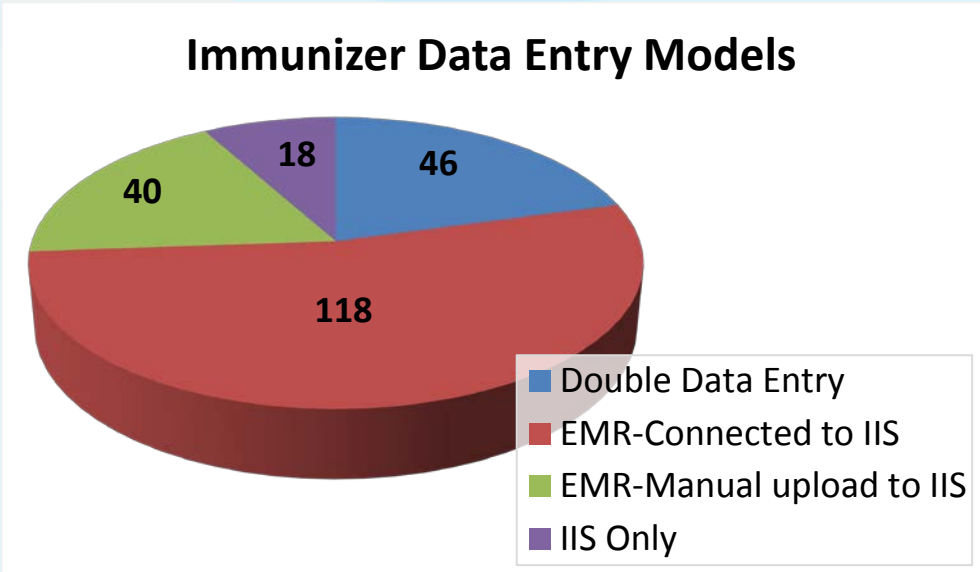
- **Manufacturers and original August 1st vaccines**
  - Sanofi – Menactra, Pediatric DT
  - GSK – HAVRIX Adult
- **New 2D Vaccines**
  - Sanofi - Adacel, Fluzone, Daptacel, Tenivac, IPOL, Pentacel
- **Providers - Immunizers**
  - 222 immunizers enrolled
  - 13 selected for work flow analysis (WFA)
- **CDC Immunization Program Grantees**
  - 10 enrolled

Participating Immunization Grantees

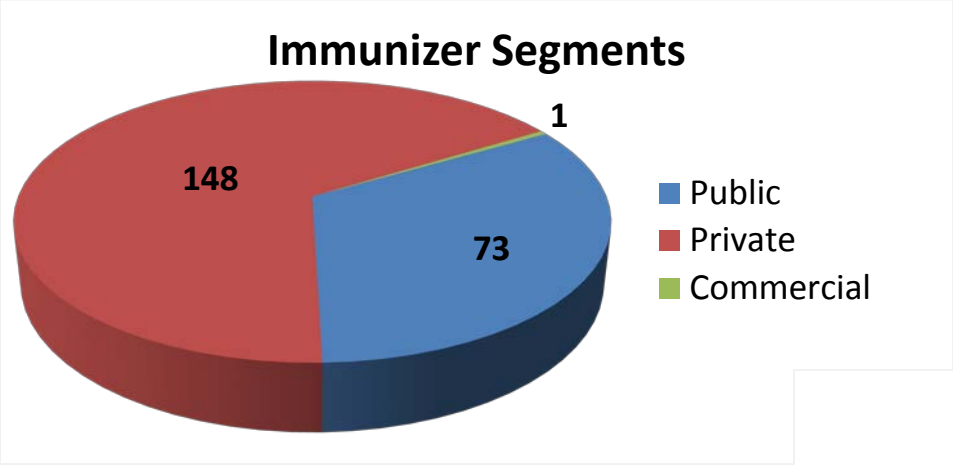


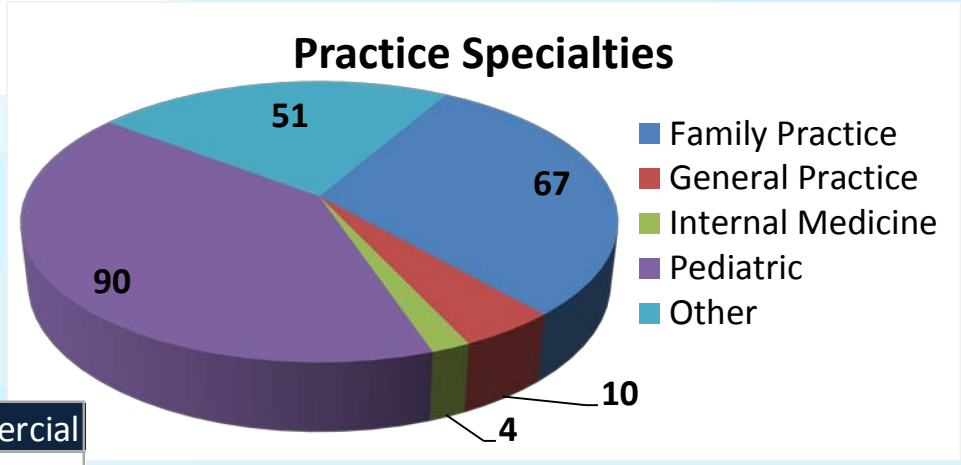
Immunizer Demographics





Immunizer Demographics





	Public	Private	Commercial
Family Practice	13	54	0
General Practice	8	2	0
Internal Medicine	0	4	0
Pediatric	4	84	0
Other	48	2	1

- *Over 70% of "Other" are Public Health Departments*
- *The single commercial practice is a commercial pharmacy that administers vaccinations.*

EMR Types in the Pilot

EMR Vendor	Total
AllScripts	45
Amazing Charts	1
Cerner	2
e-Addabbo	5
eClinical Works	27
e-MD	5
Encounter Pro	1
EPIC	19

EMR Vendor	Total
GE Centricity	5
Insight Netsmart	13
Medent	24
Mitchell & McCormick	3
NetPractice	1
NextGen	12
Office Practicum	16
Practice Partner	2

EMR Vendor	Total
Praxis	2
Profiler (Unicare)	4
QS1	1
RPMS	7
Sage Intergy	5
SIS	3
SuccessEHS	2
No EMR	17

Fully integrated 2D scanning capabilities

Partially integrated 2D scanning capabilities

No integrated 2D scanning capabilities

Evaluation Phase of Pilot

Evaluation Components

1. Accuracy and Completeness
2. User Feedback
3. Workflow Analysis

Data: 2D and linear barcoded vaccination data

Data Sources: IIS records, EMR records, Shipping manifests, Vaccine inventory logs, Manufacturer product logs

Analysis: Descriptive and inferential statistics, Confidence intervals, T-tests, Linear regression

Workflow Analysis

Purpose: To help understand the impact of 2D scanners and barcoded products on vaccine administration and inventory processes

Pre-2D State Mar 2012 – May 2012	Post-2D State Jan 2013 – Mar 2013
• No 2D barcoded technology • Limited or scanning procedures • 2D barcoded vaccines not available	• 2D barcoded technology in place • 2D scanning procedures matured • 2D barcoded vaccines in supply

Approach: Process maps, time measurements and staff interviews collected before and after the introduction of 2D capabilities provide the basis to measure the effected change.

Workflow Analysis – Example Summary Findings

Standards: Inventory and vaccination procedures have minimal variance regardless of practice size or type

Opportunities: Similar EMR functional enhancement requests were observed in most practices.

Challenges: Adoption may lag - reluctance to change established procedures

Perceptions: Interviews - candid practitioner expectations and thoughts

"Really it is the best thing that has happened for the practice with respect to vaccines. We have been asking for it for 8 years."

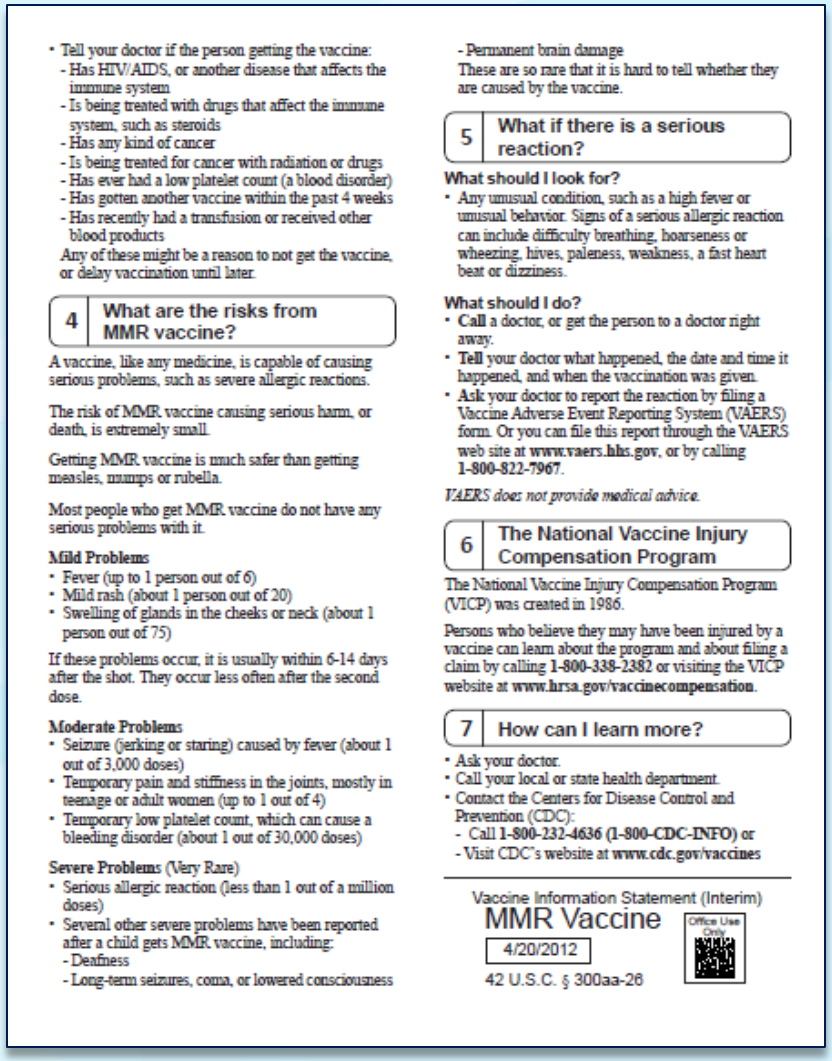
"This new process will be more about accuracy; not so much a time saver."

"For high volume practices the time savings will be great. It adds up to a small lunch break every week."

"As I am getting older they make the numbers smaller"

VIS 2D Barcoding

- Identified barcode
  - Selected GS1's Global Document Type Identifier (GDTI) to encode VIS document type
  - Added VIS edition date to GS1 DataMatrix
- Developed frequently asked questions for users
- CDC VIS Barcode Web-page
- Rolling out barcodes on new VIS



- Tell your doctor if the person getting the vaccine:
  - Has HIV/AIDS, or another disease that affects the immune system
  - Is being treated with drugs that affect the immune system, such as steroids
  - Has any kind of cancer
  - Is being treated for cancer with radiation or drugs
  - Has ever had a low platelet count (a blood disorder)
  - Has gotten another vaccine within the past 4 weeks
  - Has recently had a transfusion or received other blood products

Any of these might be a reason to not get the vaccine, or delay vaccination until later.

4 What are the risks from MMR vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions.

The risk of MMR vaccine causing serious harm, or death, is extremely small.

Getting MMR vaccine is much safer than getting measles, mumps or rubella.

Most people who get MMR vaccine do not have any serious problems with it.

Mild Problems
- Fever (up to 1 person out of 6)
- Mild rash (about 1 person out of 20)
- Swelling of glands in the cheeks or neck (about 1 person out of 75)

If these problems occur, it is usually within 6-14 days after the shot. They occur less often after the second dose.

Moderate Problems
- Seizure (jerking or staring) caused by fever (about 1 out of 3,000 doses)
- Temporary pain and stiffness in the joints, mostly in teenage or adult women (up to 1 out of 4)
- Temporary low platelet count, which can cause a bleeding disorder (about 1 out of 30,000 doses)

Severe Problems (Very Rare)
- Serious allergic reaction (less than 1 out of a million doses)
- Several other severe problems have been reported after a child gets MMR vaccine, including:
  - Deafness
  - Long-term seizures, coma, or lowered consciousness
  - Permanent brain damage

These are so rare that it is hard to tell whether they are caused by the vaccine.

5 What if there is a serious reaction?

What should I look for?
- Any unusual condition, such as a high fever or unusual behavior. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?
- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**.

7 How can I learn more?

- Ask your doctor.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at **www.cdc.gov/vaccines**

Vaccine Information Statement (Interim)
MMR Vaccine
4/20/2012
42 U.S.C. § 300aa-26

2dbarcodepilot.com

Resources for the
Two-Dimensional (2D) Vaccine Barcoding Community

Search

Immunization Providers | Immunization Grantees | Vaccine Manufacturers

Quick Links

- Pilot Overview and Information
- Educational Forum Information and Registration (Under Construction)
- Manufacturers Forum, Resources and Archives

Source: Sanofi Pasteur

2D Vaccine Barcode Pilot Resources

In September 2011, the Centers for Disease Control and Prevention (CDC) initiated a 2D vaccine barcoding pilot project to assess the challenges and to determine the best practices for labeling and tracking vaccines using 2D barcodes.

Here you will find materials and resources as they become available to support the pilot participants and the vaccine barcoding community at large.

For your convenience, pilot findings and relevant industry reports are listed here on the home page. Follow the appropriate links to find supporting materials, updates, and news.

The resources will grow as the pilot continues, so please check back often.

Resource Library:

Industry Resources

AAP
- Barcoding Clinician Guide
- AAP & GS1 Healthcare US Guidelines for Suppliers: The Application of GS1R DataMatrix Barcodes to Vaccines for Point of Care

FDA
- FDA Guidance For Industry

Pilot Findings
- Manufacturers Forum Final Report, 3/1/12 [PDF-12MB/107 pages]

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Pilot Updates
- **Pilot Newsletters**
- 8/2012 August 2012 Monthly Update [PDF, 101KB/2 pages]
- 7/2012 July 2012 Monthly Update [PDF, 149KB/2

Important Dates
- **TBD**

Educational Forum, please watch for dates

All Important Dates

Industry News
- **8/2012** Sanofi Pasteur to Add 2D Barcode to Six More Vaccines
- **7/2012** Sanofi Pasteur

http://www.2dbarcodepilot.com

Thank You-Happy Scanning

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333
Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov Web: www.cdc.gov